

REMARKS

The following remarks are responsive to the Official Action mailed August 11, 2006.

In the Official Action, the Examiner rejects claims 25-29 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description. The Examiner contends that the phrase "positioning means" has no antecedent basis in claim 25 and is therefore new matter. The Examiner acknowledges that the Applicant appears to be invoking 35 USC § 112, sixth paragraph, but for some reason, the Examiner asserts that it may be an improper assertion if only one structure for performing the "means" is disclosed.

Applicants concur with the Examiner's contention in that they are trying to invoke 35 U.S.C. § 112, sixth paragraph in using the term "positioning means". But the Applicants are puzzled as to why the Examiner rejects to this and further are puzzled as to why the Examiner asserts that it may be improper if only one structure for performing the "means" is disclosed. The Examiner has not highlighted any specific part of the M.P.E.P. which supports his contention. Thus, Applicant asserts that claims 25-29 are acceptable as written.

Claims 1-33 are rejected under 35 U.S.C. § 103(a) as being unpatenable over U.S. Patent Application Publication 2002/0143328 to *Shluzas et al.* This reference was cited in the previous Official Action. The Examiner cites *Shluzas* and asserts that it discloses most of the elements of the claims for which it is cited against, however, the Examiner acknowledges that it does not disclose a stopping element separable and adjustable as included within the claims of the present application. The Examiner asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the stopping element (240) separate

from the shaft of the bone screw. With all due respect to the Examiner, Applicants respectfully traverse this rejection.

In *Shluzas*, the bone screw includes a fixed stopping element or barrier. The stopping element limits the position of a bone plate relative to the bone screw. Since the stopping element is part of the bone screw, the plate can only be positioned in one specific location relative to the screw. Further, the stopping element in *Shluzas* includes wrenching flats 34. The wrenching flats consist of flat side walls that enable a wrench or other instruments to be applied to the screw. Once a wrench is attached to the wrenching flats, the wrench may be turned to apply or torque to the screw. The resultant force causes the screw to rotate, enabling the screw to be embedded within a bone. If the stopping element was not affixed to the screw, the wrenching flats would not be able to aid in providing a torque to the screw.

Therefore, a person skilled in the art would not be motivated to provide a stopping element that may be adjusted along a longitudinal axis of a bone anchor. This is because if they were, they would lose the ability to apply a force against the wrenching flats so as to rotate and embed the screw within a bone unless additional features were included. Thus, one having *Shluzas* at their disposal would not be motivated to alter, nevermind have a stopping element that includes a bore enabling the stopping element to translate along the longitudinal axis of the bone fastener as included claim 1 of the present application. Similarly, independent claim 25 of the present application includes a "positioning means" that enables a height of the bone plate relative to a vertebral body to be adjusted without movement of a bone fastener. This feature is also not disclosed in *Shulzas* as once again *Shulzas* discloses a stopping element, which is affixed to a point on the bone screw. And a plate may only be positioned adjacent to the stopping element

while being disposed on the bone screw. Thus, Applicants assert that independent claims 1 and 25 as well as their dependent claims are patentably distinct over *Shluzas* and should be deemed allowed.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

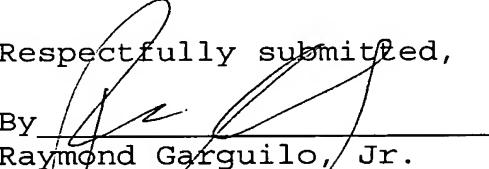
If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: October 30, 2006

Respectfully submitted,

By


Raymond Garguilo, Jr.
Registration No.: 50,930
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorney for Applicant